# Proposed Decision Memo for Non-Autologous Blood Derived Products for Chronic Non-Healing Wounds (CAG-00190R)

## Decision Summary

CMS is correcting section 270.3 of the national coverage determination (NCD) manual, entitled “Blood-Derived Products for Chronic Non-Healing Wounds,” by proposing to delete the following sentences, “Coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous non-healing wounds, will remain at local carrier discretion. Becaplermin is approved by the Food and Drug Administration.” The correct statement should read “Coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous wounds, will remain nationally non-covered.”

We are requesting comments on these changes.

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## Proposed Decision Memo

TO: Administrative File: (CAG-#00190R)
Non-Autologous Blood Derived Products for Chronic Non-Healing Wounds

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SUBJECT: Proposed Coverage Decision Memorandum for Non-Autologous Blood Derived Products for Chronic Non-Healing Wounds

DATE: February 13, 2006

## I. Proposed Decision

CMS is correcting section 270.3 of the national coverage determination (NCD) manual, entitled “Blood-Derived Products for Chronic Non-Healing Wounds,” by proposing to delete the following sentences, “Coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous non-healing wounds, will remain at local carrier discretion. Becaplermin is approved by the Food and Drug Administration.” The correct statement should read “Coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous wounds, will remain nationally non-covered.”

We are requesting comments on these changes.

## II. Background

After releasing a national non-coverage determination on Autologous Blood-Derived Products for Chronic Non-Healing Wounds in December of 2003, an error was printed in the NCD manual. The error reads, “Coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous non-healing wounds, will remain at local carrier discretion.” While CMS makes every effort to provide accurate and complete information, the erroneous coverage statement printed in the NCD manual regarding non-autologous blood-derived products was not intended and not part of the Decision Memorandum posted on December 15, 2003.[1] Non-autologous blood-derived products are not in the same class as the products referred to in the December 15, 2003 Decision Memorandum.

The stages of wound healing are sequential in the normal healing process of acute wounds. Since, the etiology of wounds vary, the most effective therapy may vary as well. Wound care must be directed at providing an environment in which the body can affectively carry out the healing process. Chronic wound therapy involves local wound care and systematic measures. (Decision Memo, CAG-00190N)

**III. History of Medicare Coverage**

In 1992, CMS issued a national non-coverage determination for platelet-derived wound healing formulas. The decision was based in part on a review conducted by the Office of Health Technology Assessment in the Agency for Health Care Policy and Research dated July 1992 (AHCPR Pub. No. 92-0065).

In April 2003, CMS determined that autologous platelet rich plasma (PRP) was sufficiently different from platelet-derived growth factor (PDGF) and should not fall under the 1992 national non-coverage determination. The differences noted in the CMS review included: PRP contains whole cells and PDGF does not contain cells; PRP is marketed as a process and is used by physicians in a clinical or surgical setting; but PDGF has been marketed as a product to be used at home by patients. Therefore, questions regarding the efficacy of autologous PRP continued to arise. As a result, on May 8, 2003, CMS began the NCD process for autologous blood-derived products for chronic, subcutaneous non-healing wounds.

On December 15, 2003, CMS issued a national non-coverage determination for autologous blood-derived products for chronic, subcutaneous non-healing wounds. CMS determined that the evidence was adequate to conclude that autologous PDGF in platelet-poor plasma does not improve healing in chronic subcutaneous non-healing wounds and, therefore, is not reasonable and necessary. This national non-coverage determination also included autologous platelet-rich plasma (PRP) due to the absence of specific evidence of benefit demonstrating autologous PRP is reasonable and necessary for the treatment of chronic subcutaneous non-healing wounds. In light of the absence of data on the health outcomes of this treatment with PRP, CMS issued a national non-coverage determination for use PRP except when used in accordance with the clinical trial policy defined in section 270.3 of the NCD Manual.

This NCD manual included the statement that the utilization of becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous wounds, remains at local carrier discretion. CMS is proposing that becaplermin, remains nationally non-covered.

Although the NCD issued on December 15, 2003 included the misprint in reference to becaplermin, CMS, pursuant to local carrier discretion, has not made payments for treatments utilizing non-autologous platelet-derived wound healing formulas (e.g. becaplermin) for the years 2002-2004 and the first quarter of 2005.

## Benefit Category Determination

For an item or service to be covered by the Medicare program, it must meet one of the statutorily defined benefit categories outlined in the Social Security Act. There is no independent Medicare benefit category for non-autologous PDGF products administered topically. These products, when self-administered, have no benefit category.

## IV. Timeline of Recent Activities

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| 12/15/03 | Issued national non-coverage determination on autologous blood derived products for chronic wound healing. |
| 07/23/04 | Issued NCD instructions for carriers in the NCD manual with incorrect language stating coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous wounds, will remain at local carrier discretion. |
| 06/23/05 | Received a decision of “no independent benefit category” from the Centers for Medicare Management on the use of non-autologous PDGF for chronic non-healing wounds. |
| 09/29/05 | CMS opens this national coverage determination (NCD). |
| 02/13/06 | CMS released the Proposed Decision Memorandum for this NCD and is requesting final comments. |

## V. FDA Status

The FDA approved the first biotechnology product to treat deep diabetic foot and leg ulcers in December of 1997. Becaplermin was approved for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond, and have an adequate blood supply.[2]

## VI. Public Comments

CMS received a total of three public comments. The first commenter suggests that CMS include treatment with autologous bone marrow in the decision memorandum. However, the use of aspirated bone marrow to facilitate spine healing is not relevant to the topic of the current proposed decision memorandum.

The second comment was received from the distributor of Regranex Gel (a becaplermin product), Ethicon, Inc. Ethicon, Inc. agrees that the reference to Regranex Gel (becaplermin) in the December 2004 non-coverage determination on autologous blood-derived products was in error. They also suggest that CMS clarify the classification of Regranex Gel to clearly state it is not a platelet-derived growth factor. CMS has clearly stated that becaplermin is a non-autologous growth factor.

The third commenter requested that CMS address platelet rich plasma (PRP) products that are used intraoperatively to control bleeding and aid in wound healing. In response, CMS did address the PRP products in the December 2004 decision memorandum on autologous blood-derived products. CMS determined, in the absence of specific evidence of benefit that there is not sufficient evidence to conclude that autologous PRP is reasonable and necessary for the treatment of chronic non-healing cutaneous wounds. Additionally, this proposed decision memorandum is not addressing the treatment of acute surgical wounds.

## VII. Analysis

Becaplermin when self-administered, has no benefit category, therefore it cannot be covered under the Medicare program. The language placed in the coverage manual was in error and needs to be corrected.

## VIII. Conclusion

CMS is correcting section 270.3 of the national coverage determination (NCD) manual, entitled “Blood-Derived Products for Chronic Non-Healing Wounds,” by proposing to delete the following sentences, “Coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous non-healing wounds, will remain at local carrier discretion. Becaplermin is approved by the Food and Drug Administration.” The correct statement should read “Coverage for treatments utilizing becaplermin, a non-autologous growth factor for chronic non-healing subcutaneous wounds, will remain nationally non-covered.”

We are requesting comments on these changes.

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[1] The Decision Memorandum posted on December 15, 2003 referenced becaplerin in section II of the memorandum, stating: “In 1997, FDA approved the biologics license application of Ortho-McNeil Johnson Pharmaceuticals, Inc. to market Regranex ® (becaplermin) Gel 0.01%. The recombinant human platelet-derived growth factor-BB (rhPDGF-BB) was approved for the treatment of lower extremity diabetic neuropathic ulcers that extend into subcutaneous tissue or beyond and have an adequate blood supply. It was not approved for superficial ulcers that do not extend through the dermis into subcutaneous tissue or ischemic diabetic ulcers. **Since becaplermin is not an autologous product, we have elected to not address this product in this decision memorandum.**”

[2] Retrieved on October 14, 2005 from http://www.fda.gov/cder/biologics/products/becaomj121697.htm

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